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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/502,479

07/23/2004

Patrick Wuthrich

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12/31/2008

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EXAMINER

MERCIER, MELISSA S

ART UNIT

PAPER NUMBER

1615

MAIL DATE

DELIVERY MODE

12/31/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/502,479	Applicant(s) WUTHRICH ET AL.	
	Examiner MELISSA S. MERCIER	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Summary

Receipt of Applicants Remarks filed on September 15, 2008 is acknowledged. Claims 11-23 remain pending in this application. In view of Applicants Disclosure of a joint research agreement between the instant assignee and Roquette Freres which is disclosed as being in effect on December 21, 2001, the Serpelloni reference is therefore excluded. The rejection over Serpelloni has been withdrawn.

Maintained Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 16 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant has not provided adequate written description of the broad claim of flow agent. A review of Applicants specification discloses one example, colloidal silica. The disclosure of only one example does not disclose structural or functional linkages in

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order for one of ordinary skill in the art to distinguish what would be considered a flow agent.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear if applicant is claiming one or more lubricants OR flow agents or one or more lubricants AND flow agents. Clarification is requested. For purposes of examination, the examiner has interpreted the limitation to be a lubricant OR a flow agent.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive. Applicant argues it is the position of the Office that Claim 16 lacks written description for flow agents generally and that Claim 16 lacks enablement for lubricants. The Office acknowledges the specification disclosure of colloidal silica as a flow agent. Moreover, the Office notes the disclosure in the cited US Patent No. 7,201,922 of magnesium stearate as lubricant. The applicant consequently relies on the fact that these substances and their function in pharmaceutical compositions are well known in the art and that the Specification comprises adequate written description of flow agents, generally, and enablement of lubricants, specifically. It is unclear what Applicants'

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arguments regarding the enablement of lubricants are intended to encompass. There is no rejection for enablement of record in the instant application. It appears applicant has confused the 112, 2nd rejections with an enablement rejection. The disclosure of one flow agent without a description of what functional properties and characteristics would be encompassed by the term flow agent. It is thus the position of the examiner that applicant has provided written description for colloidal silica specifically and not flow agents generically.

Newly Applied Rejections

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 11-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Luhn US 6770368 in view of Wikipedia Perindopril Product Information Disclosure.

Luhn teaches using granules consisting of lactose and starch (col. 2, lines 38). Example 2 discloses numerous examples of starch/lactose tablets having hardness factors with the ranges claimed in instant claims 19-20, which dissolve in less than 3 minutes and preferably less than 1 minute as recited in claims 12-13. If a lower hardness was desired one of ordinary skill in the art would be motivated to modify the ratio of lactose to starch to achieve the desired hardness and it would be obvious to optimize the formulation through routine experimentation to achieve a tablet with the desired hardness.

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Regarding claim 16, Example 2 additionally discloses the tablets tested comprise magnesium stearate, which is a lubricant.

Regarding claims 17-18, Luhn discloses tablets made with the co dried granules (column 3, lines 64-68) using an AM type Frogerais alternating press which uses direct compression.

The granules can be used in pharmaceutical preparations (col. 3, line 44). Luhn teaches the generically that the granules can be used in pharmaceutical formulations. One of ordinary skill in the art would be motivated to look to the prior art for suggestions of active ingredients to use in making a rapidly dissolving tablet.

Luhn does not disclose the specific use of perindopril.

Wikipedia discloses perindopril is used as an ACE inhibitor and is commonly administered in dosages of 2-10mgs for the treatment of high blood pressure.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have used co-dried starch and lactose granules to make a tablet for pharmaceutical use because Luhn teaches the granules impart reduced friability, efficient flow, good tableting capacity and satisfactory disintegrating properties (col. 2, lines 30-35). One of ordinary skill in the art at the time the invention was made would have been motivated to use any pharmaceutical in a tablet formulation exhibiting satisfactory disintegrating properties especially when it is desired for the pharmaceutical to be delivered rapidly in order for the therapeutic effect to quickly take affect. One of ordinary skill in the art would be motivated to use perindopril in the pharmaceutical dosage form because it is effective for reducing blood pressure.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 11-23 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 10-16 and 18-21 of copending Application No. 10/502,593. Although the conflicting claims are not identical, they are not patentably distinct from each other because the only differences between the two applications are the active agent. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have substituted any active agent into the formulation in order to obtain the desired therapeutic benefits.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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Claims 11-23 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 11-18 and 20-23 of copending Application No. 10/502,594. Although the conflicting claims are not identical, they are not patentably distinct from each other because the only differences between the two applications are the active agent. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have substituted any active agent into the formulation in order to obtain the desired therapeutic benefits.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 11-23 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 7,201,922. Although the conflicting claims are not identical, they are not patentably distinct from each other because the only differences between the two applications are the active agent. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have substituted any active agent and to optimize the percentage of the active agent in the formulation in order to obtain the desired therapeutic benefits.

Conclusion

Due to the new grounds of rejection presented in this office action, this action is made non-final. Any inquiry concerning this communication or earlier communications

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from the examiner should be directed to MELISSA S. MERCIER whose telephone number is (571)272-9039. The examiner can normally be reached on 8:00am-4:30pm Mon through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melissa S Mercier/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615